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10/665,514	09/22/2003	Marius Hauri	01000165	5820
21395 LOUIS WOO LAW OFFICE OF LOUIS WOO 717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314			EXAMINER WITCZAK, CATHERINE	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/665,514  
Filing Date: September 22, 2003  
Appellant(s): HAURI ET AL.

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Louis Woo  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 2/27/2009 appealing from the Office action mailed 12/1/2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

#### **(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: There is a typographical error in appellant's statement. Claims 5 and 24 (rather than 5 and 27) stand rejected under 35 USC 103(a) as being unpatentable over Crawford in view of Hudon and further in view of Johnson et al.

#### **WITHDRAWN REJECTIONS**

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 6 and 25 under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Hudon as applied to claims 1 & 20 and further in view of Pressly, Sr. et al has been withdrawn.

#### **NEW GROUND(S) OF REJECTION**

Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Hudon and in further view of Johnson et al as applied to claims 5 and 24 and further in view of Pressly, Sr. et al.

### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

### **(8) Evidence Relied Upon**

2002/0161336	CRAWFORD et al	10-2002
7,156,825	HUDON	1-2007
5,490,841	LANDIS	2-1996
5,669,889	GYURE et al	9-1997
2002/0010433	JOHNSON et al	1-2002
7,014,622	PRESSLY et al	3-2006

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-2, 4, 9, 20-21, 23, and 28 are rejected under 35 U.S.C. 102(e) as being unpatentable over Crawford et al (US 2002/0161336A1) as modified by Hudon (US 7,156,825).

Crawford discloses a safety apparatus in Figures 1-14 comprising a needle hub 60 having a proximal portion and a distal portion, a needle 40 extending from a distal end of said needle hub; a collar 90 mounted directly on the distal portion of said needle hub, said collar having a first engage mechanism 97 at its inner circumferential surface; a housing 140 pivotally connected to said collar; and a needle sheath 50 having a proximal portion with a second engage mechanism 56 at its outer circumferential surface, said first and second engage mechanism fitted to each other when said sheath is fitted to said collar, said proximal portion having only one side in contact engagement to said collar for covering said needle extending from the distal end of said needle hub and said sheath is not in contact with said needle hub when said sheath is fitted to said collar and said first and second engage mechanism are engaged to each other.

With respect to claims 2 and 21, see figure 12.

With respect to claims 4 and 23, wherein second engage mechanism 56 comprises a groove and first engage mechanism 97 comprises a rib, see figures 2, 9, and 10.

With respect to claims 9 and 28, wherein the collar has a lock mechanism 118 and wherein the housing has another lock mechanism 194 for coaxing to fixedly retain the housing.

Crawford et al disclose the claimed invention except for the collar being rotatably mounted on the needle hub. Hudon discloses in Figure 3 that it is known to use a collar 2 which is rotatably mounted on a needle hub, see also column 3, lines 35-43. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Crawford et al with a rotatably mounted collar as taught by Hudon since such a modification would allow a user to retrofit a conventional needle assembly with the inventive rotatable collar 2 to provide an inexpensive needle protection device (see column 4, lines 17-30).

2. Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Hudon as applied to claims 1 and 20 and further in view of Landis (US 5,490,841). The Crawford reference as modified by Hudon discloses the claimed invention except for overlapping housing lips with off-centered openings. Landis teaches the use of overlapping housing lips with off-centered opening in figures 9A-B and 11. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Crawford as modified by Hudon in order to easily entrap the needle within the housing.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Hudon as applied to claims 1 and 20 and further in view of Gyure (US 5,669,889). The Crawford reference as modified by Hudon discloses the claimed invention except for lock mechanisms on the collar and housing utilizing an aperture. The Gyure reference teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (elements 61 and 57, Figure 3). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure in the apparatus of Crawford as modified by Hudon in order to provide a lock mechanism for one-way safety locking to prevent re-exposure of the needle after covering.

4. Claims 5 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Hudon as applied to claims 1 and 20 and further in view of Johnson (US 2002/0010433). The Crawford reference as modified by Hudon discloses the claimed invention except for a ring spaced around the hub end for a user to grasp. The Johnson reference teaches a ring spaced around a hub end for a user to grasp (Figures 2a-e). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Johnson in the apparatus and method of



Crawford as modified by Hudon in order to facilitate connection of the hub and barrel.

5. Claims 11, 13-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (US 2002/10010433) in view of Crawford et al as modified by Hudon and further in view of Pressly, Sr. et al. The Johnson reference discloses a needle hub with a luer connector 68 and a ring 42 graspable by a user to remove the needle hub from a syringe surrounding, in a spaced relation, to the luer connector, see Figures 2A-F. Now even though Johnson does not explicitly disclose a collar and a needle sheath attention is directed to Crawford as modified by Hudon. The Crawford reference teaches a needle hub 60 having a luer connector and a needle 40 on the distal end of the hub; a collar 90 having a housing 140 pivotally connected thereto directly fitted to and rotatable about said distal portion of the needle hub, and a needle sheath 50 having a proximal portion with only one side in contact engagement to said collar, said needle sheath not in contact with said needle hub and removable from said collar to expose said needle for use. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Johnson with the teachings of Crawford as modified by Hudon in order to provide a shielding apparatus to help prevent accidental punctures by the needle. Now even though Johnson does not explicitly disclose a window in the

ring, attention is directed to Pressly, Sr. et al. The Pressly, Sr. et al reference teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of the needle hub, see Figure 10 and column 7 lines 35- 43, wherein the transparency would be deemed a window. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Johnson in view of Pressly, Sr. et al in order to provide a window via a transparent ring in order to see if the device has been properly connected. Also see rejection above with respect to Crawford as modified by Hudon.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (in view of Crawford et al as modified by Hudon in view of Pressly, Sr. et al as applied to claim 11 and further in view of Landis. The Johnson in view of Crawford as modified by Hudon reference discloses the claimed invention except for overlapping housing lips with off-centered openings. Landis teaches the use of overlapping housing lips with off-centered openings in Figures 9A-B and 11. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus in order to easily entrap the needle with the housing.

#### **NEW GROUND(S) OF REJECTION**

7. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al as modified by Hudon in further view of Johnson as applied to claims 5 and 24 and further in view of Pressly, Sr. et al (US 7,014,622). Even though Crawford as modified by Hudon do not explicitly disclose a window attention is directed to Pressly, Sr. et al. The Pressly, Sr. et al reference teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of the needle hub, see Figure 10 and column 7 lines 35-43, wherein the transparency would be deemed a window. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Crawford as modified by Hudon in view of Pressly, Sr. et al in order to provide a window via a transparent ring in order to see if the device has been properly connected.

#### **(10) Response to Argument**

With respect to Appellant's arguments that Hudon does not disclose a collar which is rotatably mounted on a needle hub, Examiner disagrees in that Hudon discloses in Figure 3 a collar (2) which is rotatably mounted on a needle hub (28), see also column 4, lines 35-43. The collar (2) of Hudon is then held onto the needle hub through the use of flange (24) which overlies flange (26) of the hub (26). In response to Appellant's argument that the substitution of Hudon's collar (2) in for element (90) in Crawford's device would run counter to the

teachings of Crawford, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Crawford to be used with a collar as taught by Hudon (i.e. being rotatably mounted on the needle hub) while retaining all the other functional characteristics of the original Crawford device, as incorporating a rotatable collar into the Crawford device would provide for a collar which can easily be retrofitted onto a needle hub to provide a safety assembly.

Appellant argues that Crawford does not disclose the second engage mechanism to be a circumferential groove and the first engage mechanism to be a rib. Examiner again disagrees. There is no special definition of these terms in the specification. It is the Examiner's position that under the broadest reasonable interpretation the helical thread and corresponding groove of Crawford meet the limitation of a rib (the raised portion of the thread) and a circumferential groove (the area in between the threads). Although the application discloses the circumferential rib and groove being capable of being

snapped together, Appellant has neither clearly defined the terms "rib" and "groove" to only include a structure in which the two can only be mated by being snapped together, nor has the Appellant recited this specific limitation in any claim so as to narrow the definition of the terms 'rib' and 'groove' to exclude the threaded portions of Crawford's device from meeting these limitations.

Appellant argues that Landis does not teach lips being angled toward the interior of the housing with the angle of the lips being varied along the length of the housing. Examiner disagrees and points Appellant to Figure 11 where the angle of lip 120A (which extends the length of the housing) is varied from that of lip 120B (which also extends the length of the housing).

Appellant further argues that the combination of Crawford, Hudon and Johnson would not be feasible. Examiner disagrees. While Appellant argues that Johnson discloses a syringe hub, Examiner points to Figure 2F and paragraph [0042] where Johnson discloses the adapter assembly being used with medical instruments such as needle hubs.

Regarding the Pressly, Sr. reference, Appellant argues that because the transparent needle assembly (8) of the Pressly, Sr. reference is used in a syringe with a specially designed needle hub (i.e. not a luer connector) and that because the needle assembly is permanently joined to the syringe barrel it would not be obvious to combine the teaching of Pressly, Sr. with the teachings of Crawford as modified by Hudon and in view of Johnson. Examiner disagrees.

It is well known to those of ordinary skill in the art that needle hub connections in syringes are readily interchangeable, and so the mere fact that the device of Pressly, Sr. does not disclose the use of a luer hub is not significant, as the teaching of a transparent window as disclosed by Pressly, Sr. is applicable to any syringe, regardless of the type of needle hub connector the syringe uses.

Appellant's arguments hinge upon the reasoning that it would not be possible to combine the cited prior art teachings because of the structural incompatibilities of the various devices. However, Examiner notes that the features which Appellant is claiming are known features within the syringe art, as well as the fact that, as pointed out above, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. It would be well within the realm of one having ordinary skill in the art at the time the invention was made to modify the structural dimensions of the elements of the teachings Hudon, Johnson, Landis, Pressly, Sr. and Gyure so as to be able to incorporate them into the device of Crawford in such a way as to retain the full functionality of the original elements of Crawford's design while providing the device of Crawford with the improvements stemming from the incorporation of the prior art teachings.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in

compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,  
  
/Catherine N Witczak/  
  
Examiner, Art Unit 3767

**A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:**

/DONALD HAJEC/  
  
Director, Technology Center 3700



Conferees:

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767

/Janet C. Baxter/  
TC 3700 TQAS